

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Shin-ichiro KOBAYASHI et al. Group Art Unit : Not Yet Assigned  
Appl. No. : 10/500,463 (U.S. National Phase of PCT/JP03/00251) Examiner : Not Yet Assigned  
Filed : July 14, 2004  
For : PHARMACEUTICAL COMPOSITION COMPRISING 2,2-DICHLORO-12-(4-CHLOROPHENYL)-DODECANOIC ACID

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
U.S. Patent and Trademark Office  
220 20th Street S.  
Customer Window, Mail Stop \_\_\_\_\_  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

Sir :

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicants hereby bring the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited and discussed in the specification, the International Search Report, the Written Opinion, and the International Preliminary Examination Report issued in connection with counterpart International Patent Application No. PCT/JP03/00251. Copies of the International Search Report (in English and Japanese), the Written Opinion (in Japanese) and the International Preliminary Examination Report (in Japanese) were enclosed with the papers when entering the National Stage on July 14, 2004. The Examiner is invited to review these materials to inspect the relevance indicated during international examination

with respect to the documents cited therein. The following is a list of the documents cited in the above-noted documents:

(1) Japanese Laid-Open Patent Publication No. 10-510515, which was published on October 13, 1998, together with a partial English language translation of the same.

Applicants note that this document is cited in the specification of the present application including pages 1 and 3; and

(2) Japanese Laid-Open Patent Publication No. HEI 5-952, which was published on January 8, 1993, together with an English language Abstract of the same.

(3) Applicants also bring to the Examiner's attention the following documents which were cited in U.S. Patent Application No. 10/849,778 (a copy of which is enclosed herewith), which discloses subject matter related to that of the present application:

(4) Expert Opinion on Investigational Drugs, "*Insulin Sensitiser Drugs*," Vol. 9, No. 6, pp. 1347-1361, 2000;

(5) European Journal of Medicinal Chemistry, "*ω-Substituted Alkyl Carboxylic Acids As Antidiabetic and Lipid-Lowering Agents*," Vol. 33, pp. 775-787, 1998;

(6) Metabolism, "*BM 17.0744: A Structurally New Antidiabetic Compound With Insulin-Sensitizing and Lipid-Lowering Activity*," Vol. 48, No. 1, pp. 34-40, January 1999;

(7) Journal of Medicinal Chemistry, "*The Effect of 1,3-Diaryl-[1H]-pyrazole-4-acetamides on Glucose Utilization in ob/ob Mice*," Vol. 44, pp. 2601-2611, July 6, 2001;

(8) Journal of Clinical Investigation, "*Glucose Transporter Levels in Spontaneously Obese (db/db) Insulin-resistant Mice*," Vol. 85, pp. 962-967, March 1990;

(9) Arzneimittel-Forschung, "Effects of Pioglitazone on Glucose and Lipid Metabolism in Normal and Insulin Resistant Animals," Vol. 40, pp. 156-162, 1990;

(10) Archives of Toxicology, "Species Differences in Induction of Hepatic Enzymes by BM 17.0744, An Activator of Peroxisome Proliferator-Activated Receptor Alpha (PPAR $\alpha$ )," Vol. 73, pp. 440-450, 1999;

(11) U.S. Patent No. 5,968,982 to VOSS et al., which issued on October 19, 1999; and

(12) U.S. Provisional Patent Application No. 60/472,737, which was filed on May 23, 2003 and is the parent of U.S. Patent Application No. 10/849,778. Applicants note that this provisional application is a copy of the Japanese priority document of the U.S. patent application, and thus a copy is not being provided herewith.

Further to the U.S. Patent and Trademark Office's decision to waive the requirement under 37 C.F.R. §1.98 (a)(2)(i), a copy of the U.S. patent (document 11) is not enclosed herewith. However, if a copy is needed, the Examiner is respectfully requested to contact the undersigned.

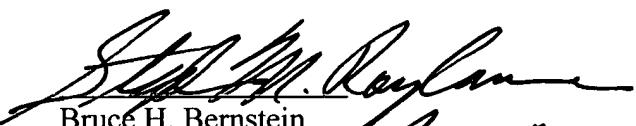
Applicants respectfully request that the Examiner consider the above material and cite the same. Copies of documents (1)-(10) are attached hereto and documents (1), (2), and (4)-(11) are listed on the attached PTO-1449 Form. Applicants note that documents (3) and (12) are not listed on the PTO-1449 Form as they are unpublished documents. The Examiner is requested to initial the appropriate spaces on the attached Form and to return a copy of the completed Form to Applicants with the next official communication in the present application.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted

material. However, if an Office Action on the merits has issued and is crossing this statement in the mail, the undersigned hereby authorizes the Commissioner to charge any fee necessary for the consideration of this statement, including any payment under 37 C.F.R. §1.17 (p) to Deposit Account No. 19-0089.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
Shin-ichiro KOBAYASHI et al.

  
Bruce H. Bernstein  
Reg. No. 29,027  
31,096

October 13, 2004  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191

FORM PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
P25616Application No.  
10/500,463INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT  
(Use several sheets if necessary)Applicant  
10/500,463Filing Date  
July 14, 2004Group  
Unknown

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5	9	6	8	9	8	2	10/19/99	VOSS et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	10	-	5	1	0	5	1	5	10/13/98	JAPAN			X
			5	-	9	5	2		01/08/93	JAPAN			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	1	English Language Abstract of JP 5-592.
	2	Expert Opinion on Investigational Drugs, "Insulin Sensitiser Drugs," Vol. 9, No. 6, pp. 1347-1361, 2000.
	3	European Journal of Medicinal Chemistry, " $\omega$ -Substituted Alkyl Carboxylic Acids As Antidiabetic and Lipid-Lowering Agents," Vol. 33, pp. 775-787, 1998.
	4	Metabolism, "BM 17.0744: A Structurally New Antidiabetic Compound With Insulin-Sensitizing and Lipid-Lowering Activity," Vol. 48, No. 1, pp. 34-40, January 1999.
	5	Journal of Medicinal Chemistry, "The Effect of 1,3-Diaryl-[1H]-pyrazole-4-acetamides on Glucose Utilization in ob/ob Mice," Vol. 44, pp. 2601-2611, July 6, 2001.
	6	Journal of Clinical Investigation, "Glucose Transporter Levels in Spontaneously Obese (db/db) Insulin-resistant Mice," Vol. 85, pp. 962-967, March 1990.
	7	Arzneimittel-Forschung, "Effects of Pioglitazone on Glucose and Lipid Metabolism in Normal and Insulin Resistant Animals," Vol. 40, pp. 156-162, 1990.
	8	Archives of Toxicology, "Species Differences in Induction of Hepatic Enzymes by BM 17.0744, An Activator of Peroxisome Proliferator-Activated Receptor Alpha (PPAR $\alpha$ )," Vol. 73, pp. 440-450, 1999.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.